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PTO/SB/08A (10-96)

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Substitute for form 1449A/PTO			Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			Application Number	09/972,219 6/623,239
			Filing Date	10/04/2001
			First Named Inventor	Fitzhugh et al.
			Group Art Unit	1616
			Examiner Name	Unassigned
Sheet 2 of 3	Attorney Docket Number		17363-20	

5837313	11/17/1998	Ding et al.
5837736	11/17/1998	Mitchell et al.
5840759	11/24/1998	Mitchell et al.
5877216	03/02/1999	Place et al.
5891459	04/06/1999	Cooke et al.
5910316	06/08/1999	Keefer et al.
5945452	08/31/1999	Cooke et al.
5958427	09/28/1999	Salzman et al.
5962520	10/05/1999	Smith et al.
5994444	11/30/1999	Trescony et al.
6024918	02/15/2000	Hendriks et al.

FOREIGN PATENT DOCUMENTS								
Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publications of Cited Documents MM/DD/YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Office <sup>2</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
166		WO	00/02501		William Harvey Research LTD.	01/20/00		

OTHER PRIOR ART / NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume/issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
166		Bauer et al.; Evaluation of Linear Polyethyleneimine/nitric Oxide Adduct on Wound Repair: Therapy versus Toxicity; Wound Repair & Regeneration, November/December 1998, pp. 569/577		
		Chandy et al; "Use of Plasma Glow for Surface/Engineering Biomolecules to Enhance Bloodcompatibility of Dacron and PTFE Vascular Prosthesis." Biomaterials 21: 699/712		
		Drago; "Free Radicals in Inorganic Chemistry." No. 36, Advances in Chemistry Series, American chemical society, Washington, D. C. 1962, pp. 143/149		
		Hanson et al; Nitric Oxide Donors: A Continuing Opportunity in Drug Design; Advances in Pharmacology, Vol 34, pp. 383/398		
		Hrabie et al; "New Nitric Oxide/Releasing Zwitterions Derived from Polyamines." J. Org. Chem. 1993, 58, 1472/1476		
166		Jordi; Jordi Gel Columns for Size Exclusion Chromatography; Column Handbook for Size Exclusion Chromatography; 1999, pp. 367/425		
Examiner Signature		Blessing Furber		Date Considered
				12/12/04

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<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent documents. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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Sheet	1	of	3	Attorney Docket Number	17363-20

U.S. PATENT DOCUMENTS						
Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Date of Publications of Cited Documents MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup>			
BF		4954526		09/04/1990	Keefer	
		5039705		08/13/1991	Keefer et al.	
		5155137		10/13/1992	Keefer et al.	
		5171217		12/15/1992	March et al.	
		5212204		05/18/1993	Keefer et al.	
		5229172		07/20/1993	Cahalan et al.	
		5250550		10/05/1993	Keefer et al.	
		5268465		12/07/1993	Bredt et al.	
		5366997		11/22/1994	Keefer et al.	
		5380758		01/10/1995	Stamler et al.	
		5405919		04/11/1995	Keefer et al.	
		5428070		06/27/1995	Cooke et al.	
		5468630		11/21/1995	Billiar et al.	
		5482925		01/09/1996	Hutsell	
		5519020		05/21/1996	Smith et al.	
		5525357		06/11/1996	Keefer et al.	
		5574068		11/12/1996	Stamler et al.	
		5583101		12/10/1996	Stamler et al.	
		5632981		05/27/1997	Saavedra et al.	
		5650447		07/22/1997	Keefer et al.	
		5658565		08/19/1997	Billiar et al.	
		5676963		10/14/1997	Keefer et al.	
		5683668		11/04/1997	Hrabie et al.	
		5691423		11/25/1997	Smith et al.	
		5700830		12/23/1997	Korthuis et al.	
		5714511		02/03/1998	Saavedra et al.	
		5718892		02/17/1998	Keefer et al.	
		5721365		02/24/1998	Keefer et al.	
		5770645		06/23/1998	Stamler et al.	
		5789447		08/04/1998	Wink, Jr. et al.	
		5814656		09/29/1998	Saavedra et al.	
BF		5814667		09/29/1998	Mitchell et al.	
Examiner Signature		Blessing Fubara			Date Considered	12/14/04

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		Filing Date	10/04/2001
		First Named Inventor	Fitzhugh et al.
		Group Art Unit	1616
		Examiner Name	Unassigned
Sheet 3 of 3	Attorney Docket Number	17363-20	

bf	Kaul et al.; Polymeric/Based Perivascular Delivery of a Nitric Oxide Donor Inhibits Intimal Thicening After Balloon Denudation Arterial Injury: Role of Nuclear Factor/kappaB; Journal of the American College of Cardiology, Vol. 35, No. 2, 2000:493/501	
	Keefer et al.; "NONOates" (1/Substituted Diazen/1/ium/1,2/diolates) as Nitric Oxide Donors: Convenient Nitric Oxide Dosage Forms." Methods in Enzymology, Vol 268: 281/293	
	Mowery et al.; Preparation and Characterization of Hydrophobic Polymeric Films That Are Thromboresistant Via Nitric Oxide Release; Biomaterials 21 (2000) 9/21	
	Saavedra et al.; "Conversion of Polysaccharide to Nitric Oxide/Releasing Form Dual/Mechanism Anticoagulant Activity of Diaseniumdiolated Heparin." Bioorganic & Medicinal Chemistry Letters 10 (2000) 1/3	
bf	Smith et al.; Nitric Oxide/Releasing Polymers Containing the [N(O)NO] <sup>+</sup> Group; J. Med. Chem. 1996, 39, 1148/1156	

Examiner Signature	Blessing Eubana	Date Considered	12/12/04
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OC: 147482 v01 02/26/2002

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Application Number	10/623,239
Filing Date	7/17/2003
First Named Inventor	Fitzhugh et al.
Group Art Unit	1616
Examiner Name	Unassigned
Attorney Docket Number	P497 CON 1 (14364-0099)

Sheet	1	of	1
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## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publications of Cited Documents MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
BF		WO	0030658	A1	Smith et al.	06/02/2000		

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
BF		Downey et al.; Growth Mechanism of Poly(divinylbenzene) Microspheres in Precipitation Polymerization; American Chemical Society, Easton, US, Vol. 32, No. 4, 4 May 1999; pgs 2838-2844	
BF		Pulfer et al.; Incorporation of Nitric Oxide-Releasing Crosslinked Polyethyleneimine Microspheres into Vascular Grafts; Journal of Biomedical Materials Research; Wiley, New York, NY, Vol. 37, No. 2, November 1997 (1997-11); pp. 182-189	
BF		Zhang et al.; Synthesis of Nitric Oxide Releasing Silicone Rubbers for Biomedical Applications; Polymer Preprints; Vol. 40, No. 2, 1999, pgs 799-800	

Examiner Signature	Blessing Fubara	Date Considered	12/12/04
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2.0 hours to complete, including gathering, preparing, and submitting the completed application or to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, Patent and Trademark Office, US Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 240945US0DIV		SERIAL NO. New Application	
LIST OF REFERENCES CITED BY APPLICANT				APPLICANT Yoshinao NAGASHIMA, et al.			
				FILING DATE Herewith		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA						
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	AM						
	AN						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES                  NO		
	AO	WO 1/58435 A1	8/16/01	WIPO			
	AP	0 183 436 A2	11/13/85	EPO			
	AQ	H10-25245	1/27/98	JAPAN			
	AR	H11-343497	12/14/99	JAPAN			
	AS	H4-128234	4/28/92	JAPAN			
	AT	H6-40911	2/15/94	JAPAN			
	AU	H5-255688	10/5/93	JAPAN			
	AV	2000-42125	2/15/00	JAPAN			
	AW	H10-113369	5/6/98	JAPAN			
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AX	Toshimitsu MUSHA, Ph.D., Shin KIMURA, M.S., Ken-Ichi KANEKO, Kiyoka NISHIDA, and Kazuo DEKINE, Emotion Spectrum Analysis Method (ESAM) for Monitoring the Effects of Art Therapy Applied on Demented Patients, CybrPsychology & Behavior, Vol. 3, No. 3, 2000, pp. 441-446, Mary Ann Liebert, Inc.					
	AY	Kazuhiko SAWADA, Ryoichi KOMAKI, Yoshikuni YAMASHITA, Yasushi SUZUKI and Seichi ISHIYAMA, Physiological Effects of Volatile Components in Forest, Kanebo Co. Ltd. Cosmetic Laboratory and Research Institute of Human Engineering for Quality Life, Odawara 250-0002.					
	AZ	A Manual of Standardized Terminology, Techniques and Scoring System for Sleep Stages of Human Subjects; Allan Rechtschaffen, et al., 1968.					
					<input checked="" type="checkbox"/> Additional References sheet(s) attached		
Examiner <i>L. Channavayale</i>					Date Considered <i>12/9/04</i>		
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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AAA	Abstract, Patent No. JP 10025245, Application No. JP 96182349, January 27, 1998, "Oral Hypnotic Agent used for Medicines, Foods, Drinks and Feeds Contain Essential Oil of Sandalwood."					
	AAB	Abstract, Patent No. JP 11343497, Application No. JP 98188008, December 14, 1999, "Cosmetics Showing Sedative and Hypnotic Effect Comprising Flavour of Rosemary, Lavendar, Bitter Orange or Senkyu."					
	AAC	Abstract, Patent No. JP 4128234, Application No. JP 90249716, April 28, 1992, "New Sleep Promoting Agent Comprising Bitter Orange Essential Oil, Formulated for Absorption through the Nasal Mucosa or the Lungs."					
	AAD	Abstract, Patent No. JP 6040911, February 16, 1994, Application No. JP 92195333, July 22, 1992, "Sleep Promoter Containing Jasmine Lactone as Active Component is in the Form of Preparation where Active Component is Absorbed from Lung or Nose or Mouth Mucosa."					
	AAE	Abstract, Patent No. JP 5255688, October 5, 1993, Application No. JP 9289811, March 13, 1992, "Perfume Containing Sedative Essential Oil has Durable Sedative Effect."					
	AAF	Abstract, Patent No. JP 10113369, May 6, 1998, Application No. 9770225, March 24, 1997, (WO 9807403), "Cosmetological Method for Achieving Valuable Cosmetic Effects Easily by Massage Comprising Massage Carried Out by Ordinary People Along Arterial and then Venous Blood Flow Paths using Cosmetic Containing Disintegrative Particles."					
	AAG	Sawada, et al., 132CA:332157, 1999.					
	AAH	Binet, et al., 78CA:24110, 1972.					
	AAI						
	AAJ						
	AAK						
	AAL						
	AAM						
	AAN						
	AAO						
	AAP						
	AAQ						
Examiner		Channarayana				Date Considered 12/9/04	
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LIST OF RELATED CASES

<u>Docket Number</u>	<u>Serial or Patent Number</u>	<u>Filing or Issue Date</u>	<u>Inventor/ Applicant</u>
240950US0-DIV	10/646,825	08/25/03	NAGASHIMA, et al.
240945US0-DIV* ---	10/645,554	08/22/03	NAGASHIMA, et al.

L. Channarayana

12/9/04